



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,294	05/31/2006	Revel Michel	REVEL17	3323
1444 7590 09/27/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER WANG, CHANG YU	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 09/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/560,294

Applicant(s)

REVEL ET AL.

Examiner

Chang-Yu Wang

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to a method of generating oligodendrocytes.

Group II, claim(s) 10, drawn to isolated oligodendrocytes.

Group III, claim(s) 20, 23-29, drawn to a pharmaceutical composition comprising  
ES/EB/NS cells and one or more gp130 activators.

Group IV, claim(s) 21-22, drawn to a pharmaceutical composition comprising  
ES/EB/NS cells and an expression vector encoding a gp130 activator.

Group V, claim(s) 30-36, drawn to a culture medium.

Group VI, claim(s) 37-39, drawn to a method of treatment of demyelinating  
disease by oligodendrocytes.

Group VII, claim(s) 40-45, 51-53, drawn to a method of treating a demyelinating  
disease comprising administration of ES/EB/NS cells and one or more gp130  
activators.

Group VIII, claim(s) 46-50, drawn to a method of treating a demyelinating  
disease by administering ES/EB/NS cells and an expression vector of a gp130  
activator.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The 1<sup>st</sup> claimed invention is drawn to a method of generating oligodendrocytes comprising embryonic stem, embryoid bodies and/or neurospheres and a gp130 activator such as CNTF or IL-6, which is anticipated by prior art references. Shimazaki et al. disclosed a method of culturing neural stem cells in the presence of CNTF and CNTF limits neural stem cells to glial progenitor cells including oligodendrocytes (see p. 7642, abstract; p. materials and methods, Shimazaki et al. J Neurosci. 2001. Oct 1; 21: 7642-53), which meets the limitation of the 1<sup>st</sup> claim. MacDonald et al. disclosed a method of culturing oligodendrocytes from neural precursor cells of E15-E18 mouse embryos, which including neural stem cells, in the presence of CNTF (see p.256, Materials and methods, MacDonald et al. J. Neurosci. Res. 2002. 68:255-264). In addition, as also found in the International Search Report, the Invention of the Group I was found to have no special technical feature that defined the contribution over the prior art of Zhang et al. (see p. 244, abstract, Stem cells 2004. 22:244-354, as in IDS) and WO03/059376 (published on Jul 24, 2003 as in IDS; see p. 5). Zhang et al. and WO03/059376 teach culturing oligodendrocytes from embryonic stem cells in the presence of IL-6, which meets the limitation of the claim 1. Therefore, claim 1 is anticipated by Shimazaki et al., MacDonald et al., Zhang et al. and WO03/059376. Since the 1<sup>st</sup> claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions. Thus, Applicant's inventions

do not contribute a special technical feature when view over the prior art, they do not have a single inventive concept and so lack unity of invention.

In addition Group I is directed to a technical feature of a method of generating oligodendrocytes. Group II is directed to a technical feature of isolated oligodendrocytes. Group III is directed to a technical feature of a pharmaceutical composition comprising ES/EB/NS cells and one or more gp130 activators. Group IV is directed to a technical feature of a pharmaceutical composition comprising ES/EB/NS cells and an expression vector encoding a gp130 activator. Group V is directed to a technical feature of a culture medium. Group VI is directed to a technical feature of a method of treatment of demyelinating disease by oligodendrocytes. Group VII is directed to a technical feature of a method of treating a demyelinating disease comprising administration of ES/EB/NS cells and one or more gp130 activators. Group VIII is directed to a technical feature of a method of treating a demyelinating disease by administering ES/EB/NS cells and an expression vector of a gp130 activator.

Therefore, the above Inventions do not share a common special technical feature as they comprise different steps and utilize different products, which demonstrates that each method has a different mode of operation and use of structurally and functionally divergent materials. For example, a method for treating patients does not have a same corresponding technical feature as that in a method of making oligodendrocytes because the patients are not required in the method of making oligodendrocytes. Accordingly, Groups I-VIII are not so linked by the same or a corresponding special

Art Unit: 1649

technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept.

### ***Species Election***

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

i. If any group from Groups I-VIII is elected, Applicant is required under PCT Rule 13.2 to elect a single disclosed species of gp130 activator selected from A) CNTF, B) OSM, C) IL-6/IL6R-IL6 chimera or D) IL-11 recited in claims 1-3, 20-24, 30-32, 40-42 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

ii. If Group I or Group IV is elected, Applicant is required under PCT Rule 13.2 to elect a single disclosed species of oligodendrocytes selected from A) O1+ or B) O4+ oligodendrocytes recited in claims 7-8, 33-34 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 30 are generic.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The technical

features of these species are different because each specific species differs with respect to its composition and structures. For gp130 activator, each specific species differs with respect to its composition and structures. For oligodendrocytes, the cell contents and biological characteristics in O1+ oligodendrocytes are different from those of O4+ oligodendrocytes. Consequently the responses to different biomolecules are also different in these different types of cells. Therefore, these species do not share a common corresponding technical feature; and thus lack unity of invention.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-VIII and a single species from groups i-ii that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected group and species.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.



All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1649

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

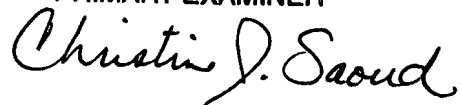
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/

Chang-Yu Wang, Ph.D.

September 14, 2007

CHRISTINE J. SAUD  
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Christine J. Saud".